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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/591,409	09/01/2006	Marc Waeterschoot	DECLE90.001APC	2495

20995 7590 08/17/2009
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EXAMINER

EPPS -SMITH, JANET L

ART UNIT	PAPER NUMBER
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1633

NOTIFICATION DATE	DELIVERY MODE
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08/17/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/591,409	Applicant(s) WAETERSCHOOT, MARC	
	Examiner Janet L. Epps-Smith	Art Unit 1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14 and 21-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-14, 21 and 31-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9-1-06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election of Group III, claims 22-30 in the reply filed on 05/27/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).
2. Claims 1-14, 21, and 31-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 05/27/2009.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
4. Claims 25 and 29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 25 recites wherein said postnatal tissue is isolated from remote areas of the body of the patient, since the term "remote" is a relative term, and therefore the scope of the term is unclear.
6. The term "remote" in claim 25 is a relative term which renders the claim indefinite. The term "remote" is not defined by the claim, the specification does not

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provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

7. Claim 29 recites the limitation “further treated using stem cell technologies,” the metes and bounds of this phrase are vague and indefinite, the ordinary skilled artisan would not be reasonably apprised of the scope of the claimed invention.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 22-23, 25-27, and 29-30 are rejected under 35 U.S.C. 102(b) as being anticipated by Boyse et al. (US 5,004,681).

Claim 22, and those claims dependent therefrom recite the following:

22. (Original) A method for the preservation of viable postnatal stem and/or progenitor cells for use in a method of treatment of a disease or a disorder of a patient, comprising the steps of: a) isolating post-natal tissue from a patient comprising stem and/or progenitor cells, b) optionally, separating the stem cells and/or progenitor cells from said postnatal tissue, and, c) cryopreserving/freezing the tissue of step a) or the cells of step b) in a solid support such that said tissue or cells remain(s) viable.

Applicants describe “post-natal” sampling as wherein said sampling taken after the birth of the individual, see the instant specification at page 3, 1st full ¶.

10. Boyse et al. describe the isolation of stem and progenitor cells in the blood of newborn humans or animal, therefore the isolated cells of this reference are interpreted

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as reading on the "post-natal" tissue comprising stem and/or progenitor cells according to the present invention.

11. Boyse et al. teach a method for the preservation of fetal and neonatal hematopoietic stem and progenitor cells, wherein the cells are cryopreserved. The invention also provides the therapeutic use of such stem and progenitor cells upon thawing. In particular, the present invention relates to the therapeutic use of fetal or neonatal stem cells for hematopoietic (or immune) reconstitution (see abstract).

12. Claim 25 recites wherein said postnatal tissue is isolated from remote areas of the body of the patient, since the term "remote" is a relative term, and therefore the scope of the term is unclear, the teachings of Boyse et al. which comprise the isolation of hematopoietic stem cells from cord blood or bone marrow, see section 5.1.3.1, is interpreted as reading on the claimed invention.

13. § 6.10.1 of Boyse et al. teach wherein bone marrow is isolated from the femur or hip of a patient. (This portion of the reference reads on instant claim 27).

14. In regards to the handling of the stem cells, after cryopreservation and storage of the cells, once the cells are request for use in a method of treatment, the cells are withdrawn and tested for viability and microbial contamination, the cells are then quantified in terms of stem cell, progenitor cell, and other categories. This aspect of the Boyse et al. reference is considered to anticipate instant claim 29 to the extent that it teaches that the cells are "further treated using stem cell technologies."

15. § 6.11.3 of this reference demonstrate the use of stem cells in the reconstitution of the hematopoietic system of lethally-irradiated mice, this portion of the reference is

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interpreted as reading on instant claim 30 to the extent that it teaches wherein the cells are "further differentiated."

Claim Rejections - 35 USC § 103

16. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

17. Claims 22-27 and 29-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyse et al. (US 5,004,681).

18. The teachings of Boyse et al. as set forth above is incorporated here, however this reference does not teach:

24. (Currently amended) The method according to claim 22, wherein said solid support is marked by a barcode.

19. Boyse et al. teach a method for packaging and labeling cryopreserved stem cells in freezing vials and labeling the vials in computer-generated characters. Absent evidence to the contrary, it would have been obvious to the ordinary skilled artisan to substitute the labeling method described in Boyse et al. with the barcode labeling method recited in the instant claims, since the ordinary skilled artisan would have recognized that barcode labeling is a functionally equivalent means for labeling via computer generated characters. See for example MPEP§ 2144.06 [R-6].

Claim Rejections - 35 USC § 102

20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

21. Claims 22-26, and 28-30 are rejected under 35 U.S.C. 102(a or e) as being anticipated by Fraser et al. (US 2003/0054331 A1).

Fraser et al. teach the following at ¶ [0002]:

“[T]he present invention is directed to a population of adipose tissue-derived cells, specifically adipose tissue-derived stem and progenitor cells, which are cryopreserved for subsequent use and to the therapeutic uses of said cryopreserved cells.....In a preferred embodiment cells that have been cryopreserved and thawed can be used for autologous (self) repair, reconstitution, reconstruction, and diagnostic applications. The invention also relates to methods for collection, processing, and cryopreservation of the stem and progenitor cells and the connective tissue of the invention.” (This portion of the reference reads on instant claims 22-23.

The adipose tissue derived stem and progenitor cells isolated by Fraser et al. are non-embryonic or "adult" stem cells, see paragraph [0010- 0011], this portion of Fraser et al. reads on instant claims 25-26 and 28.

Fraser et al. also teach the application of a client identification barcode label to the collection container comprising the sterile tissue containing the stem and progenitor cells, see ¶ [0068], this portion of Fraser reads on claim 24.

Paragraphs [0129] through [0135] of Fraser et al. describe methods of thawing and isolation of stem cells from the cryopreserved tissue. This portion of Fraser et al. is considered to read on instant claim 29 to the extent that it teaches that the cells are "further treated using stem cell technologies."

Paragraphs [0144] through [0146] describe wherein aliquots of cyropreserved cells populations are thawed and assayed for differentiation capacity. It was demonstrated that 80.9% of the cells recovered after thawing and had the ability to differentiate along adipocytic, osteoblastic, and neuronal lineages. This portion of the reference reads on instant claim 30.

22. Claims 22-23 and 28 are rejected under 35 U.S.C. 102(e) as being anticipated by Shakhov et al. (US20040151706A1)

23. Shakhov et al. teach a method wherein bone marrow is withdrawn from the hip bone of a patient, see ¶ [0007]. This reference further teaches wherein stem cells are harvested for future autologous transplantation in the donor. See paragraph [0038] which discloses the following description of the disclosed invention of Shakhov et al.:

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“[I]n the case of bone marrow extraction, the collection can be performed such as by making one or more insertions of a syringe means into the donor's hip or pelvic bone to extract bone marrow as the biological specimen containing stem cells. Cryogenic preservation generally will be the preservation technique of choice for the harvested biological specimen that contains stem cells.”

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24. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Smith whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

25. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

26. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Smith/
Primary Examiner, Art Unit 1633